



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 9, 2013

Mr. Joseph Mercado
Regulatory Affairs Specialist
Spine Wave, Incorporated
3 Enterprise Drive, Suite 210
Shelton, Connecticut 06484

Re: K132154

Trade/Device Name: CapSure® PS System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH
Dated: July 11, 2013
Received: July 12, 2013

Dear Mr. Mercado:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Page 2 – Mr. Joseph Mercado

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Erin L. Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K132154

Device Name: CapSure® PS System

Indications for Use:

The CapSure® PS System is a non-cervical spinal fixation system intended for posterior pedicle screw fixation (T1-S2/ilium) in skeletally mature patients. The CapSure® PS System is indicated for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

The CapSure® PS System is also indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebral joint, having fusions with autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation are L3-S2/ilium), and for whom the device is intended to be removed after solid fusion is attained.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Amy S. Graf -S

(Division Sign-Off)

Division of Orthopedic Devices

510(k) Number: K132154

Page 1 of 1

000035



510(k) Summary CapSure® PS System

1. Submitter Information

Submitter: Spine Wave, Inc.
Address: Three Enterprise Drive
Suite 210
Shelton, CT 06484
Telephone: 203-712-1847
Telefax: 203-944-9493

Contact: Joseph Mercado

Date Prepared: July 11, 2013

2. Device Information

Trade Name: CapSure® PS System
Common Name: Pedicle Screw Spinal System
Classification Name: Pedicle Screw Spinal System
Classification/Code: Class II per 21 CFR 888.3070; MNI, MNH

3. Purpose of Submission

The purpose of this submission is to gain clearance for additional components to the cleared CapSure® PS System.

4. Predicate Device Information

The CapSure® PS System described in this submission is substantially equivalent to the following predicate:

Predicate Device	Manufacturer	510(k) No.
CapSure® PS System	Spine Wave, Inc.	K122233

5. Device Description

The predicate CapSure® PS System consists of a selection of non-sterile, single use, titanium alloy screws and connectors, and titanium alloy and cobalt chrome rod components that are assembled to create a rigid spinal construct. The components of the predicate CapSure® PS System are attached to the non-cervical spine of skeletally mature patients in order to stabilize the spine during fusion of vertebral bodies, and are intended to be removed after spinal fusion is achieved.

6. Intended Use

The CapSure® PS System is a non-cervical spinal fixation system intended for posterior pedicle screw fixation (T1-S2/ilium) in skeletally mature patients. The CapSure® PS System is indicated for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

The CapSure® PS System is also indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebral joint, having fusions with autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation are L3-S2/ilium), and for whom the device is intended to be removed after solid fusion is attained.

7. Comparison of Technological Characteristics

The substantial equivalence of the subject CapSure® PS System is shown by similarity in intended use, indications for use, materials and performance to the cited predicate device.

8. Performance Data

The modified implants were compared to constructs previously tested in static compression, static torsion and dynamic compression in accordance with ASTM F1717. An engineering rationale determined that the proposed implants do not represent a new worst case and were therefore determined to be substantially equivalent to the predicate devices.

9. Conclusion

Based on the indications for use, technological characteristics and comparison to a predicate, the subject CapSure® PS System has been shown to be substantially equivalent to the predicate device identified in this submission, and does not present any new issues of safety or effectiveness.